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EXAMINER	
DEAK, LESLIE R	

ART UNIT	PAPER NUMBER
3761	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/826,736	MATSON ET AL.	
	Examiner	Art Unit	
	LESLIE R. DEAK	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 December 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *4/16/04* is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/26/06, 10/5/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1-3 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0 787 500 A1 to Wratten et al.

In the specification and figures, Wratten discloses the device substantially as claimed by applicant. With regard to claims 1-2 and 5, Wratten discloses a hemofiltration system that is capable of treating the illness as claimed by applicant. The system comprises a hemofilter 5 that is capable of removing ultrafiltrate from a bloodstream 3, creating a filtered blood stream at 9 and an ultrafiltrate stream at 8. The system further comprises adsorptive device 11/12 that receives ultrafiltrate and is capable of removing inflammatory mediators to create an postadsorption ultrafiltrate stream. The adsorbent material may be material having activated carbon, hydrophobic or ion exchange resins, and combinations thereof (see p1 of specification, FIG 1). The device further comprises tubing that is used to combine the postadsorption ultrafiltrate stream with the filtered blood stream in a reservoir 4 for return to the patient.

Wratten fails to specifically disclose that the postadsorption ultrafiltrate stream may be "selectively" combined with the filtered blood stream. Applicant's claim language is drawn to a functional recitation—that is a recitation of what the apparatus does, not what it is. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the

claimed structural limitations. See MPEP 2114. In the instant case, the applicant has not set forth any structural limitations that allow for the claimed "selective" combination of the postadsorption ultrafiltrate steam with the filtered blood stream. Either tubing line 8 or 9 may be removed from the reservoir 4 in the Wratten device, providing the claimed "selective" combination. As such, the apparatus disclosed by Wratten, with some manipulation by one of ordinary skill in the art, is capable of being operated as claimed by applicant, satisfying the limitations of the claims.

With respect to claim 3, it is well known in the art that ultrafiltrate refers to filtered plasma water, solutes, and molecules such as blood peptides and proteins that are passed through the filter membrane to create the filtrate. Furthermore, Wratten specifically discloses that the filtrate comprises cytokines, which, by definition, are proteins and peptides.

3. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0 787 500 A1 to Wratten et al in view of US 5,162,102 to Nogawa et al.

In the specification and figures, Wratten discloses the apparatus substantially as claimed by applicant (see rejection above) with the exception of the materials used for the filter membrane and the housing.

Nogawa discloses a standard hollow-fiber blood filter in which the housing is constructed of a hydrophobic polycarbonate (see column 2, lines 5-19) and the filter material may comprise polysulfone, polyacrylonitrile, and cellulose (see column 3, lines 55-60). It would have been obvious to one having ordinary skill in the art at the time of invention to use the materials disclosed by Nogawa in the apparatus disclosed by Wratten, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its

suitability for the intended use as a matter of obvious design choice. See MPEP § 2144.07. Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to use the materials disclosed by Nogawa in the apparatus disclosed by Wratten, since Nogawa discloses that such materials are appropriate for use in blood filters.

4. Claims 6-8, 10-13, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0 787 500 A1 to Wratten et al in view of US 5,846,419 to Nederlof.

In the specification and figures, Wratten discloses the apparatus substantially as claimed by applicant (see rejection above) with the exception of a "means for selectively combining" the filtered blood and postadsorption ultrafiltrate for return to the patient.

With regard to applicant's claim 6, the language appears to be an attempt to invoke 35 USC 112, 6th paragraph interpretation of the claims. A claim limitation will be interpreted to invoke 35 U.S.C. 112, sixth paragraph, if it meets the following 3-prong analysis:

(A) the claim limitations must use the phrase "means for " or "step for; "

(B) the "means for " or "step for " must be modified by functional language; and

(C) the phrase "means for " or "step for " must not be modified by sufficient structure, material or acts for achieving the specified function.

In the instant case, applicant appears to have met the limitations set forth in MPEP § 2181, and examiner has turned to the specification for clarification.

In the specification, applicant defines the "means for selectively combining" as tubing, valves, and pumps that are operable to selectively control the combination. Accordingly, the examiner is interpreting the "means for selectively combining" to encompass tubing, valves,

and their equivalents. Equivalent structures may include those that perform the function specified in the claim, structures that are not excluded by any specific definition provided in the specification for an equivalent, or is a structural equivalent of the corresponding element disclosed in the specification. See MPEP 2183.

Nederlof discloses a hemofiltration system comprising a hemofilter 12, ultrafiltrate line 24 that can be diverted to secondary filter 60 by means of pumps and valves (see FIG 2). The valves and substituate pump 106 control the flow of the twice filtered diasylate through filter membrane 52 into reservoir 78 to be combined with filtered blood to return to the patient via line 85. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to add "means for selectively combining" comprising tubes, valves, and pumps as disclosed by Nederlof, to the hemofiltration system disclosed by Wratten in order to control the flow of substituate fluid to the returned blood line, as taught by Nederlof.

With regard to applicant's limitation that the ultrafiltrate stream comprises "plasma water, electrolytes, peptides, and small proteins...," Wratten discloses that the ultrafiltrate stream comprises cytokines (see Wratten, p2, lines 50-55), which are, by definition, small proteins and peptides that act as inflammatory mediators.

With regard to claims 7 and 10, Wratten discloses that the adsorbent material may be material having activated carbon, hydrophobic or ion exchange resins, and combinations thereof (see Wratten p1 of specification, FIG 1).

With respect to claim 8, it is well known in the art that ultrafiltrate refers to filtered plasma water, solutes, and molecules such as blood peptides and proteins that are passed through the filter membrane to create the filtrate. Furthermore, Wratten specifically discloses that the filtrate comprises cytokines, which, by definition, are proteins and peptides.

With regard to claim 11, Wratten discloses that the adsorbent filter creates a postadsorption ultrafiltrate stream without the inflammatory mediators, cytokines, in the post filter stream 8 (see Wratten p 3, lines 35-42). Further, Wratten and Nederlof suggest the apparatus substantially as claimed by applicant with the exception of a second pump to transfer a portion of the postadsorptive filtrate stream that is not returned to the patient to a drain. However, Nederlof discloses that various pumps and control schemes are operable to control the fluid flow through the system, and further discloses drain line 90. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to use a pump to direct unused postadsorption ultrafiltrate to drain 90 in the device suggested by Wratten and Nederlof in order to prevent fluid overload to the patient.

With regard to claims 12 and 15, the adsorbent material may be material having activated carbon, hydrophobic or ion exchange resins, and combinations thereof (see Wratten p1 of specification, FIG 1).

With respect to claim 13, it is well known in the art that ultrafiltrate refers to filtered plasma water, solutes, and molecules such as blood peptides and proteins that are passed through the filter membrane to create the filtrate. Furthermore, Wratten specifically discloses that the filtrate comprises cytokines, which, by definition, are proteins and peptides.

5. Claims 9 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0 787 500 A1 to Wratten et al in view of US 5,846,419 to Nederlof, further in view of US 5,162,102 to Nogawa.

In the specification and figures, Wratten and Nederlof suggest the apparatus substantially as claimed by applicant (see rejection above) with the exception of the materials used for the filter membrane and the housing.

Nogawa discloses a standard hollow-fiber blood filter in which the housing is constructed of a hydrophobic polycarbonate (see column 2, lines 5-19) and the filter material may comprise polysulfone, polyacrylonitrile, and cellulose (see column 3, lines 55-60). It would have been obvious to one having ordinary skill in the art at the time of invention to use the materials disclosed by Nogawa in the apparatus disclosed by Wratten, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. See MPEP § 2144.07.

6. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0 787 500 A1 to Wratten et al in view of US 5,571,418 to Lee et al.

In the specification and figures, Wratten discloses a hemofiltration device comprising a first conduit 1 that directs a blood stream from a source 4 to a hemofilter 5, a second conduit 9 that directs the filtered blood stream back to the source 4, a third conduit 8 that directs the ultrafiltrate stream to an adsorption device 11/12 that contacts the ultrafiltrate stream with an adsorptive material to remove cytokines, which are inflammatory mediators, and a fourth conduit (unlabeled) that directs the postadsorptive ultrafiltrate back to the source (see FIG 1 and accompanying text).

Wratten fails to disclose that the conduits direct fluid to and from a mammal. Applicant's recitation that the conduits are "adapted to" perform a particular function are not a positive

structural recitation but require only the ability to function as claimed. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate from a prior art apparatus satisfying the claimed structural limitations. Applicant has not set forth any structural limitations that accomplish the claimed function or differentiate from the conduits disclosed by Wratten. Furthermore, Wratten but discloses that fluid may be taken and returned to the patient using known means (see Wratten, p4, lines 10-20). Accordingly, the Wratten disclosure reasonably suggests to one of ordinary skill in the art that the disclosed conduits are capable of directing fluid flow between the locations claimed by applicant, satisfying the limitations of the claims.

Wratten is silent as to the porosity of hemofilter 5. Lee discloses hemofiltration of toxic mediator-related disease comprising the steps of withdrawing blood from a mammal, filtering the blood, and returning the filtered blood to the patient (see Lee column 4, lines 32-39). The filter used by Lee may have a molecular weight exclusion limit of 100,000 to 150,000 Daltons, which is "greater then or equal to 69,000 Daltons" as claimed by applicant. Lee discloses that the larger Dalton filter improves results over the prior art smaller pore filters (see column 3, lines 15-31). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to substitute the large pore filter disclosed by Lee for the hemofilter disclosed by Wratten in order to increase treatment effects, as taught by Lee.

7. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0 787 500 A1 to Wratten et al in view of US 5,571,418 to Lee et al, further in view of US 5,846,419 to Nederlof.

In the specification and figures, Wratten and Lee disclose the apparatus substantially as claimed by applicant (see rejection above) with the exception of the merging of the first and fourth conduits to provide a combined post-treatment stream of fluid.

Nederlof discloses an extracorporeal blood treatment apparatus comprising a first conduit or patient blood supply line 82 that directs blood from a mammal to a blood filtration device 12, a second conduit 84/85 that directs fluid from the filter 12 back to the mammal, a third conduit 70 that directs ultrafiltrate from the filter to a second treatment apparatus 60, and a fourth conduit 72/85 that receives fluid from a second treatment apparatus and returns the treated fluid to the mammal. The second conduit 84 and the fourth conduit 72 merge at reservoir 78 to combine the post-treatment streams into a single stream supplied by conduit 85 for return to the mammal.

All the component parts of the instantly claimed invention are known in the prior art. The only difference is the combination of the known elements into a single apparatus by merging the return fluid lines disclosed by Wratten. This, it would have been obvious to one having ordinary skill in the art to merge the second and fourth conduits disclosed by Wratten to form a single, combined fluid stream as disclosed by Nederlof, since the operation of the Wratten device is in no way dependent on the combination of the fluid stream for patient return, and the combined fluid stream is easily used in combination with a two-fluid return apparatus to achieve the predictable results of providing a combined fluid stream to the patient.

Terminal Disclaimer

8. The terminal disclaimer filed on 13 December 2007 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of US 6,730,266 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Response to Amendment/Arguments

9. Applicant's amendment to the specification has been entered and considered.

10. The Examiner has initialed the "P" reference in the IDS dated 26 October 2006, a copy of which is enclosed. The Examiner has also considered the IDS filed 5 October 2007.

11. Applicant's amendment and arguments filed 13 December 2007 have been entered and fully considered but they are not persuasive.

12. Applicant argues that Wratten does not teach a system "to...selectively combine" two treated fluid streams or tubing "for use in selectively combining" two fluid streams. Applicant has not set forth any structural limitation that accomplishes the function of the selective combination. Wratten shows the combination of two treated fluid streams via tubing lines 8, 9, and reservoir 4. It is the position of the Examiner that either tubing line 8 or 9 disclosed by Wratten may be removed from reservoir 4, thereby providing "selective" combination of the treated fluid streams. Accordingly, the apparatus disclosed by Wratten is capable of functioning in the manner claimed by applicant, thereby satisfying the limitations of the claims.

13. Applicant argues that the Nederlof reference is drawn to a different blood treatment method than that disclosed by Wratten and claimed by Applicant, and therefore is improperly combined with the Wratten reference to reject Applicant's claims. Specifically, Wratten teaches a convection method of blood filtration, while Nederlof teaches a diffusion method of blood

filtration. The Examiner respectfully disagrees. The Examiner is looking to the Nederlof reference merely to provide evidence of tubing, valves, and pumps in extracorporeal treatment circuits that provide a selective recombination of treated fluid streams.

14. Applicant argues that Wratten teaches away from a diffusion method of blood filtration. It has been held that the disclosure of one particular alternative as an inferior choice to some other alternative for the same use does not necessarily constitute a "teaching away" from the inferior alternative. See MPEP § 2145 (X)(D)(1). In the instant case, Wratten merely discloses that the instantly disclosed method of hemofiltration combined with adsorption is faster and more efficient than the prior art dialysis systems (see Wratten p2, lines 31-36).

15. Applicant argues that Nederlof does not teach an adsorptive device operable to create a post adsorption ultrafiltrate stream as defined in claim 6. The Examiner is not relying on the Nederlof device to teach such elements. The Examiner is relying on the Nederlof device to teach a tube, valve, and pump arrangement that allows two post-treatment streams, one from either side of the filter membrane, to be ***selectively*** combined. Valve 71 and pump 76 shown by Nederlof may be operated to selectively move filtrate in lines 70 and 72 into reservoir 78 for distribution to the patient. The Examiner is relying on the Nederlof reference to merely teach that a valve or pump may be readily added to the postadsoprtion ultrafiltrate stream 8 disclosed by Wratten in order to provide ***selective*** recombination of the fluids for redistribution to a patient.

16. Applicant argues that the combination of Wratten and Nederlof fail to disclose all the elements of claim 11. However, it is the position of the Examiner that Wratten teaches the basic blood filtration, adsorption, and recombination apparatus, while Nederlof discloses that various fluid control schemes, including tubing and valves to provide selective recombination

and/or waste removal of post-treatment fluid schemes are well-known in the art of extracorporeal blood treatment. Taken together, the references reasonably suggest the apparatus claimed by applicant.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LESLIE R. DEAK whose telephone number is (571)272-4943. The examiner can normally be reached on Monday - Friday, 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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19 February 2008

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